**IN THE UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF TEXAS**
**HOUSTON DIVISION**

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| LISA GAYLE BUTLER and DAVID A. HOLLAND, individually and as personal representatives of the ESTATE OF MATY GAYLE HOLLAND, DECEASED, | § | |
| Plaintiffs, | § | |
| v. | § | CIVIL ACTION NO. H-18-898 |
| JUNO THERAPEUTICS, INC., | § | |
| Defendant. | § | |

**MEMORANDUM AND OPINION**

When medicine fails to save a young life, and instead even shortens it, what damages claims arise under state law, and how should a court respond? Maty Holland died in 2016, at age 19, after battling leukemia off and on for six years. When, after remission, her leukemia returned and did not respond to conventional treatments, Holland and her parents agreed to have her participate in a clinical trial of a drug manufactured by Juno Therapeutics. Holland died one week after receiving the experimental drug. Holland's parents, Lisa Butler and David Holland, individually and as representatives of her estate, sued Juno, seeking damages for wrongful death, strict liability, fraud, negligence, gross negligence, and breach of warranty. (Docket Entry No. 76 at ¶¶ 101–33).

After discovery, Juno moved for summary judgment, the plaintiffs responded, and Juno replied. (Docket Entry No. 100, 114, 126, 130).[1] Based on the motion, the response, the

[1] Juno filed a redacted and a separate sealed version of its summary judgment motion. (Docket Entry Nos. 100 (redacted motion), 103 (sealed motion)). The plaintiffs also filed a redacted and a separate sealed version of their response to Juno's summary judgment motion. (Docket Entry Nos. 114 (sealed), 126

voluminous record, and the applicable law, the court grants the motion and enters final judgment by separate order. The reasons are explained below.

## I. Background

### A. Factual and Procedural Background

Many of the facts are undisputed. Chimeric Antigen Receptor T-cell (CAR-T) therapy is a developing treatment for advanced blood cancers. The therapy genetically modifies a patient's white blood cells to target cancer cells. (Docket Entry No. 104-26 at 1 (Exh. 59) (sealed)). The goal is to improve the patient's condition to the point of tolerating a bone marrow or stem-cell transplant, which may ultimately cure the disease and prolong the patient's healthy life. (Docket Entry No. 104-27 at 37:4–38:6 (Exh. 79) (sealed)).

In 2007, the Memorial Sloan-Kettering Cancer Center submitted to the Food and Drug Administration an Investigational New Drug Application for a product known as "1928z CAR T cells." (Docket Entry No. 110-4 at 16).[2] With the FDA's approval, Memorial Sloan-Kettering began a Phase 1 clinical trial for 1928z in 2010. (*Id.*). Memorial Sloan-Kettering made changes to the manufacturing process for 1928z to create JCAR015, another CAR T-cell treatment. (Docket Entry No. 101-2 at 12 (Exh. 12); Docket Entry No. 104-9 at 20 (sealed); Docket Entry No. 116-1 at 11–13 (sealed); Docket Entry No. 116-3 at 10–11 (sealed)).

In 2013, Memorial Sloan-Kettering, the Fred Hutchinson Cancer Research Center, the Seattle Children's Research Institute, and affiliated medical scientists founded Juno, with the goal

(redacted)). The court refers to the redacted motion and response and to the publicly filed exhibits as the record permits.

[2] This exhibit states that Memorial Sloan-Kettering submitted an Investigational New Drug Application in 2007 for JCAR015. Because JCAR015 developed from 1928z, some documents refer to 1928z as JCAR015. (*See* Docket Entry No. 101-2 at 12 (Exh. 12) (The "1928z CAR T cell investigational drug product is now referred to as the JCAR015 investigational drug product."). Other documents distinguish the two products "to acknowledge manufacturing differences." (Docket Entry No. 104-9 at 20 (sealed)).

of developing CAR-T therapy drugs. (Docket Entry Nos. 110-1, 110-2). Memorial Sloan-Kettering provided Juno a license to develop and market JCAR015. (Docket Entry No. 110-4 at 44).

In July 2014, Juno asked to meet with the FDA to discuss starting a Phase 2 clinical trial of JCAR015. (Docket Entry No. 117-1 at 4 (sealed)). Juno submitted premeeting materials in August 2014, and the FDA provided its preliminary responses in September. (*Id.*; Docket Entry No. 116-4 (sealed)). Representatives of Juno and the FDA met a few days later, discussed multiple issues, and set follow-up plans. (Docket Entry No. 117-1 (sealed)). One issue was whether Juno's proposed changes to the manufacturing process for JCAR015 made that drug so different from 1928z that Juno would need to do a Phase 1 clinical trial on JCAR015 before the planned Phase 2 trial.

In December 2014, the FDA stated that more data was needed on the comparability between JCAR015 and 1928z. The FDA recommended that Juno "collect data from a limited number of subjects prior to initiation of a pivotal study to demonstrate comparability between the [Memorial Sloan-Kettering 1928z] and Juno manufacturing process and final products." (Docket Entry No. 117-2 at 3 (sealed)).

In January 2015, Elizabeth Smith, Juno's senior vice-president for regulatory affairs, spoke with Dr. Peter Bross and Dr. Kristen Baird of the FDA about how to gather comparability data for JCAR015. Smith summarized their discussion in a note stating, in relevant part, that Dr. Baird was concerned that "the changes [Juno was] making to the process at [Memorial Sloan-Kettering] were intended to make the product [(JCAR015)] superior/equivalent and that by making a 'superior' product, that the better binding or in vivo expansion could make it more toxic and safety would be an important consideration in the first few patients." (Docket Entry No. 117-3 at 2

(sealed)). Smith responded that "the changes . . . were not intended to make the product better, but were intended to address availability of reagents . . . and create better controls for a more consistent manufacturing process." (*Id.*; *see* Docket Entry No. 123-6 at 23–31 (sealed)). Smith also stated that, to gather comparability data, Juno would enroll patients for the Phase 2 trial, conduct an interim comparability analysis while that trial was pending, and submit the interim data to the FDA. (*Id.*). Dr. Bross and Dr. Baird stated that while Juno's proposal was "reasonable," they remained "concerned about the potential for a different safety profile with the new process." (*Id.*). However, "if [Juno] [was] able to convince the product reviewers that [JCAR015] and [1928z] are comparable, there will be less concern from the clinical reviewer perspective." (*Id.*).

On June 30, 2015, Juno submitted an Investigational New Drug Application for JCAR015. (Docket Entry No. 104-15 (Exh. 26) (sealed); Docket Entry No. 104-21 (sealed)). The short title for Juno's proposed Phase 2 clinical trial was the "Rocket Study." (Docket Entry No. 104-15 at 27 (Exh. 26) (sealed)).[3] Juno's application included: (i) the interim results of the Phase 1 clinical trial of 1928z, (*Id.* at 26–27); (ii) pretrial comparability data for JCAR015 and 1928z (not the results of Juno's proposed interim comparability analysis), (Docket Entry Nos. 104-22 (sealed), 104-23 (sealed), 104-24 (sealed)); (iii) the protocol for the Rocket Study; (iv) an Investigator's Brochure; (v) a template informed-consent form; and (vi) other required information, (Docket Entry No. 104-21 (sealed)).

Juno proposed running a "safety and efficacy analysis" on the first ten patients with morphologic disease[4] treated with JCAR015. (Docket Entry No. 104-15 at 26–27 (Exh. 26)

[3] Heather Hughes, Juno's corporate representative, testified that the Rocket Study was named in memory of a patient who received CAR-T therapy at one of the academic institutions that cofounded Juno. (Docket Entry No. 104-27 at 78:17–79:9 (Exh. 72) (sealed)).

[4] The Rocket Study defined "morphologic disease" as 5% or more lymphoblasts in the bone marrow. (Docket Entry No. 104-9 at 33 (sealed)).

(sealed)). That data would be the basis for an interim comparability analysis. (*Id.* at 27; Docket Entry No. 104-27 at 8–9 (Exh. 66) (sealed); Docket Entry No. 1104-9 at 99–100 (sealed)).

On July 23, 2015, Argaw Takele of the FDA emailed Bentley Moyer, Juno's senior director of regulatory affairs, asking where "the information about the comparability bridging, clinical study data supporting the product changes" could be found in the JCAR015 Investigational New Drug Application. (Docket Entry No. 117-4 at 4 (sealed)). Moyer responded that the data would be forthcoming as part of the interim analysis conducted partway through the Phase 2 trial. (*Id.* at 2).

On July 29, 2015, Dr. Baird approved Juno's proposed interim study for comparability data. (Docket Entry No. 104-15 (Exh. 27) (sealed); Docket Entry No. 118-1 (sealed)). The next day, Juanita Williams-Gould of the FDA notified Moyer that the agency had approved Juno's Application and that the Rocket Study could proceed. (Docket Entry No. 104-14 (Exh. 21) (sealed)).

In October 2015, Juno entered into a Clinical Study Agreement with the MD Anderson Cancer Center. (Docket Entry No. 121-1 (sealed)). Juno agreed to pay MD Anderson $38,090.00 in startup costs, along with other costs related to the Study. (*Id.* at 22–23). Juno would pay MD Anderson, not any individual doctor. (*Id.* at 20, 24). Juno and MD Anderson anticipated enrolling eight to ten patients in the Rocket Study by September 2016. (*Id.* at 2). Juno entered into similar agreements with other hospitals around the same time.

Dr. William Wierda of MD Anderson was the principal investigator of the Rocket Study at that hospital. (*Id* at 2, 18–19; Docket Entry No. 104-8 (Exh. 9) (sealed)). He and his team were responsible for enrolling patients in the Study, obtaining their informed consent, and conducting and supervising the Study. (Docket Entry No. 104-8 (Exh. 9) (sealed); Docket Entry No. 104-27

at 81:3–22 (Exh. 83) (sealed)). Dr. Wierda appointed Dr. Michael Rytting as a subinvestigator, authorizing him to obtain informed consent from potential subjects in the Study. (Docket Entry No. 104-8 at 6 (Exh. 9) (sealed); Docket Entry No. 104-27 at 81:23–82:24 (Exh. 83) (sealed)).

In December 2015, a routine checkup by Maty Holland's pediatric oncologist revealed that her acute lymphoblastic leukemia, which had gone into remission in 2014, had returned. (Docket Entry No. 104-12 (Exh. 17) (sealed); Docket Entry No. 104-14 (Exh. 20) (sealed)). Subsequent chemotherapy was unsuccessful. By May 2016, Holland's cancer had progressed to the point that she was ineligible for a stem-cell transplant and further chemotherapy was unlikely to help. (Docket Entry No. 104-27 at 107–09 (Exh. 76) (sealed); Docket Entry No. 104-26 at 107–08 (Exh. 63) (sealed)). Holland's pediatric oncologist referred her to the MD Anderson Cancer Center to explore treatment options. (Docket Entry No. 104-27 at 105–06 (Exh. 76) (sealed)). At that stage, her condition was considered incurable with conventional chemotherapy. She faced a median survival rate of approximately three months. (Docket Entry No. 104-27 at 130–31 (Exh. 78) (sealed); Docket Entry No. 104-27 at 115 (Exh. 77) (sealed)).

On May 5, 2016, Holland and her parents met Dr. Rytting at MD Anderson and discussed treatment options. (Docket Entry No. 112-3 at 35; Docket Entry No. 104-14 (Exh. 20) (sealed)). Dr. Rytting told them that MD Anderson was conducting the Rocket Study and that Holland might be eligible to participate. Dr. Rytting did not then discuss the Study in detail.

On May 16, 2016, Holland and her mother, Lisa Butler, returned to MD Anderson. (Docket Entry No. 104-3 (Exh. 4) (sealed)). They met with nurse Virginia Bayer and discussed the Rocket Study. (Docket Entry No. 104-27 at 35–36 (Exh. 68) (sealed)). The parties dispute whether Dr. Rytting attended that meeting. Butler testified that he did not. (Docket Entry No. 104-27 at 35 (Exh. 68) (sealed); Docket Entry No. 112-3 at 39–40). Bayer testified that Dr. Rytting was present

at the beginning of the meeting. (Docket Entry No. 104-27 at 19 (Exh. 67) (sealed)). Holland's medical records include a note stating that Dr. Rytting attended the meeting and that "both the patient and the mother understand that there are significant toxicities with [CAR] T-cell infusion." (Docket Entry No. 104-3 at 12 (Exh. 4) (sealed)). It is undisputed that Bayer talked with Holland and Butler about the Rocket Study. The record shows that Dr. Rytting electronically signed the note on August 5, 2016. (*Id.*).

Butler testified that, at the meeting with Bayer, she asked how the other patients enrolled in the Rocket Study had fared. (Docket Entry No. 104-27 at 36 (Exh. 68) (sealed)). According to Butler, Bayer stated that, of three patients, one had reached remission and another had died. (*Id.*). Butler did not recall what Bayer said about the third patient. (*Id.*). Butler, Bayer, and Holland also discussed the side effects that were listed in the Study's informed-consent form. (*Id.* at 37). Holland then signed that form, consenting to participate in the Rocket Study. (Docket Entry No. 104-2 (Exh. 1) (sealed)). She was the 51st participant enrolled in the Study nationwide. (Docket Entry No. 104-27 at 205 (Exh. 83) (sealed)).

Before leaving MD Anderson, on May 16, 2016, Holland and Butler had a brief introductory meeting with Dr. Wierda. (Docket Entry No. 112-3 at 37–38). According to Butler, Dr. Wierda spoke of "incredible remission rates," but he did not otherwise discuss the Rocket Study. (*Id* at 38). On May 18, Dr. Rytting added a note to Holland's May 16 medical record entry, stating that he had "examined the patient and reviewed the side effects of the proposed treatment, including the cytokine release syndrome and possible[]shock and even death." (Docket Entry No. 104-2 at 29 (Exh. 2) (sealed)).

On May 24, 2016, a Rocket Study participant at a different trial site, M.K., developed cerebral edema and died after being treated with JCAR015. (Docket Entry No. 104-5 at 3–4

(sealed)). Juno reported the death to the FDA, stating that, "[b]ased on a review of available data, the occurrence of cytokine release syndrome and the subsequent fatal neurologic event are likely related to the administration of JCAR015" and other "[p]possible contributing factors." (Docket Entry No. 104-15 at 41 (Exh. 29) (sealed)). Until then, cerebral edema had not been observed with JCAR015 or 1928z. (*Id.*; Docket Entry No. 104-19 at 21 (Exh. 48) (sealed)).

Over the next several days, Juno discussed M.K.'s death with the FDA and the Data Safety and Monitoring Board that Juno had convened for the Rocket Study[5] and filed required paperwork. (Docket Entry No. 104-5 at 4 (sealed); Docket Entry No. 104-15 (Exh. 28) (sealed); Docket Entry No. 104-16 (Exh. 37) (sealed); Docket Entry No. 104-19 (Exhs. 47, 48) (sealed)). Juno also convened a biweekly safety call with the principal investigators, including Dr. Wierda, to discuss M.K.'s death and related updates to the Rocket Study protocol. (Docket Entry No. 104-5 (sealed)).

On May 26, 2016, Juno met with the Data Safety and Monitoring Board to discuss M.K.'s death and how to continue the Study. (Docket Entry No. 104-16 (Exh. 37) (sealed)). According to the Board's minutes, Juno paused the administration of JCAR015. (*Id.* at 14). Juno further proposed having the Board review findings for three treated patients fourteen days after each received JCAR015 to determine whether to restart treatment for other patients. (*Id.* at 15). The Board approved Juno's plan on May 31, 2016, and reviewed Juno's data on June 9, 2016. (Docket Entry No. 123-5 (sealed); Docket Entry No. 104-27 (Exh. 65) (sealed)).

The Board recommended resuming the trial for the seven subjects waiting for their first JCAR015 treatment. (Docket Entry No. 104-27 (Exh. 65) (sealed)). Holland was one of those

[5] A Data Safety Monitoring Board is an independent body of experts who accumulate and review clinical data on a regular basis and advise clinical sponsors on various subjects, including the ongoing safety of trial subjects and the continuing validity and scientific merit of the clinical trial. (Docket Entry No. 104-9 at 87 (sealed); Docket Entry No. 104-26 at 82 (Exh. 58) (sealed)). Juno convened a Board for these purposes at the beginning of the Rocket Study.

subjects. The Board also stated that enrollment in the Rocket Study was on hold at each trial site until each site's Institutional Review Board approved updated informed-consent forms and the Board approved resuming enrollment. (*Id.*). The Board required the principal investigators to "verbally inform[]" all enrolled patients "of the updated safety findings" and to document the discussion on the patients' medical records. (*Id.*). After each trial site's Institutional Review Board approved an updated consent form, the patients were to sign "as soon as possible." (*Id.*).

On June 10, 2016, Juno emailed the Board's recommendations to the principal investigators. (*Id.*). Shortly thereafter, nurse Bayer called Butler and informed her that there was a new safety concern over the Rocket Study that Dr. Wierda would discuss during Holland's next visit. (Docket Entry No. 112-3 at 48). According to Butler, Bayer stated that the Study was on hold but that Holland was allowed to continue. (*Id.*). Butler asked if there was a new informed-consent form, and Bayer stated that a new form would be provided at Holland's next visit. (*Id.*).

On June 15, 2016, Holland and Butler met with Dr. Wierda at MD Anderson. (*Id.*). Butler testified that Dr. Wierda explained that: M.K. had died after developing an "extremely high fever" that was "very uncommon"; M.K. was "very, very sick with a lot of other prior diagnoses other than [Holland's]"; and those involved in the trial "had figured out why [M.K.] had died." (*Id.* at 48–49). Dr. Wierda said that he was comfortable with having Holland receive JCAR015 and asked Holland if she wanted to proceed. She said that she wanted to continue. (*Id.* at 49; *see* Docket Entry No. 104-27 at 212–15 (Exh. 83) (sealed)). Holland was not then provided a new informed-consent form because it was not yet ready. (Docket Entry No. 112-3 at 49).

On June 23, 2016, Holland received her first infusion of JCAR015. (*Id.* at 55). On June 27, her condition began rapidly deteriorating. (*Id.* at 56–57). By June 30, she had experienced a

"massive intracranial edema." (Docket Entry No. 104-19 at 3 (Exh. 45) (sealed)). Laboratory testing confirmed "[d]evastating neurological findings," and a "very poor prognosis with minimal chance of recovery." (*Id.*). Holland died on June 30, 2016, due to "severe cerebral edema," "status epilepticus," and "cytokine release syndrome." (Docket Entry No. 112-2).

On July 7, 2016, Dr. Wierda wrote an addendum to the medical record for Holland's June 15 visit to "clarify and document the discussion [he] had with [Holland] and her mother regarding safety concerns with the CAR-T at the time of this clinic visit and before [Holland] was admitted to proceed with [JCAR015 treatment]." (Docket Entry No. 104-3 at 4 (Exh. 3) (sealed)). The record addendum stated:

> [Dr. Wierda] described in detail the events regarding the recent patient [M.K.] treated on this clinical trial who was treated at another site and experienced fatal [cytokine release syndrome] related to cerebral edema. [Dr. Wierda] explained to them that this event was thought to be related to lymphodepletion and treatment with CAR-T cells, and that it had been reviewed among all the investigators and with the FDA. Their questions were answered, and [Holland] clearly stated that [s]he wished to proceed with treatment on the clinical treatment. Therefore, she was admitted and proceeded with treatment on study.

(*Id.*). Butler testified that this addendum does not accurately summarize the conversation and that Dr. Wierda had said that M.K. died because steroids were withheld in response to his fever, not that his death was related to JCAR015. (Docket Entry No. 112-3 at 49–50).

In March 2018, Holland's parents sued Juno. (Docket Entry No. 76 at ¶¶ 101–133). Their central allegation is that Juno failed to inform Holland of the risks of severe cytokine release syndrome and toxicity that accompanied JCAR015 and that, had Holland been fully informed, she would have chosen a different treatment option. (Docket Entry No. 112-3 at 14, 51). Juno now moves for summary judgment. (Docket Entry No. 100).

### B. The Summary Judgment Record

The parties have filed numerous exhibits, most of which are sealed. (*See* Docket Entry

Nos. 104, 105, 114–125). These exhibits include: Holland's medical records; emails between Juno and the FDA; emails between Juno, MD Anderson, and the doctors running the Rocket Study; MD Anderson's policies for conducting clinical trials; and Juno's Investigational New Drug Application.

The following exhibits are publicly filed:

- an Investigator's Brochure issued by Juno, dated October 27, 2015, (Docket Entry No. 101-2 at 3–57 (Exh. 12));
- the plaintiffs' first-amended responses to Juno's first requests for admission, (*Id.* at 60–63 (Exh. 84));
- press releases from Memorial Sloan-Kettering and the Fred Hutchinson Cancer Research Center about forming Juno, (Docket Entry Nos. 110-1 (Exh. 1), 110-2 (Exh. 2));
- a press release from Juno, dated June 4, 2016, (Docket Entry No. 112-5 (Exh. 55);
- Juno's 2014 and 2015 SEC Annual Report, (Docket Entry Nos. 110-3 (Exh. 3), 110-4 (Exh. 4));
- medical publications about CAR-T cell therapy, (Docket Entry Nos. 110-5 (Exh. 8), 111-1 (Exh. 13), 111-2 (Exh. 14), 111-3 (Exh. 15), 112-1 (Exh. 16));
- screenshots from Juno's website, (Docket Entry No. 110-6 (Exh. 12));
- Holland's death certificate, (Docket Entry No. 112-2 (Exh. 40);
- Butler's deposition, (Docket Entry No. 112-3 (Exh. 41)); and
- excerpts of Holland's blog, (Docket Entry No. 112-4 (Exh. 49)).

## II. The Legal Standard for Summary Judgment

"Summary judgment is appropriate only if there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." *Vann v. City of Southaven, Miss.*, 884 F.3d 307, 309 (5th Cir. 2018) (per curiam) (quotation marks omitted); Fed. R. Civ. P. 56(a). "A genuine dispute of material fact exists if a reasonable jury could enter a verdict for the

non-moving party." *Doe v. Edgewood Indep. Sch. Dist.*, 964 F.3d 351, 358 (5th Cir. 2020). The moving party "bears the initial responsibility of . . . demonstrat[ing] the absence of a genuine issue of material fact," *Jones v. United States*, 936 F.3d 318, 321 (5th Cir. 2019) (citation and quotation marks omitted), and "identifying those portions of [the record] which it believes demonstrate the absence of a genuine issue of material fact," *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986).

"Where the nonmovant bears the burden of proof at trial, the movant may merely point to an absence of evidence, thus shifting to the non-movant the burden of demonstrating by competent summary judgment proof that there is an issue of material fact warranting trial." *Lyons v. Katy Indep. Sch. Dist.*, 964 F.3d 298, 301–02 (5th Cir. 2020) (citation and quotation marks omitted). While the party moving for summary judgment must demonstrate the absence of a genuine and material factual dispute, it does not need to negate the elements of the nonmovant's case. *Austin v. Kroger Tex., L.P.*, 864 F.3d 326, 335 (5th Cir. 2017) (per curiam) (quoting *Little v. Liquid Air Corp.*, 37 F.3d 1069, 1076 n.16 (5th Cir. 1994) (per curiam)). "A fact is material if its resolution could affect the outcome of the action." *Dyer v. Houston*, 964 F.3d 374, 379 (5th Cir. 2020) (citation and quotation marks omitted). "If the moving party fails to meet [its] initial burden, the motion [for summary judgment] must be denied, regardless of the nonmovant's response." *Pioneer Expl., L.L.C. v. Steadfast Ins. Co.*, 767 F.3d 503, 511 (5th Cir. 2014) (citation and quotation marks omitted).

When the moving party has met its burden, "the nonmoving party cannot survive a summary judgment motion by resting on the mere allegations of its pleadings." *Duffie v. United States*, 600 F.3d 362, 371 (5th Cir. 2010). The nonmovant must identify specific evidence in the record and articulate how that evidence supports that party's claim. *Willis v. Cleco Corp.*, 749 F.3d 314, 317 (5th Cir. 2014). "This burden will not be satisfied by some metaphysical doubt as

to the material facts, by conclusory allegations, by unsubstantiated assertions, or by only a scintilla of evidence." *Boudreaux v. Swift Transp. Co., Inc.*, 402 F.3d 536, 540 (5th Cir. 2005) (citation and quotation marks omitted). In deciding a summary judgment motion, the court draws all reasonable inferences in the light most favorable to the nonmoving party. *Darden v. City of Fort Worth*, 880 F.3d 722, 727 (5th Cir. 2018).

## III. Analysis

The plaintiffs assert wrongful death, failure to warn, strict liability, fraud, negligence, and breach of warranty claims. Because "Texas law treats these claims as alleging a failure to warn," the court previously analyzed the strict liability, negligence, and breach-of-warranty claims together and the fraud claims separately. *Butler v. Juno Therapeutics, Inc.*, No. CV H-18-898, 2019 WL 2568477, at *9 (S.D. Tex. June 21, 2019). The same approach is used here.

### A. The Failure-to-Warn Claims

Juno asserts that it is entitled to summary judgment on the failure-to-warn claims because the learned-intermediary doctrine applies, § 82.007 of the Texas Civil Practice and Remedies Code applies, and the plaintiffs lack record evidence supporting an inference that inadequate warnings led to Holland's death. The court addresses each argument in turn.

#### 1. The Learned-Intermediary Doctrine

Juno argues that Dr. Wierda, the principal investigator for the Rocket Study at MD Anderson, and Dr. Rytting, a subinvestigator at MD Anderson, were learned intermediaries between Juno and Holland, and that Juno adequately warned them of the risks associated with JCAR015, which prevents Juno from being liable to the plaintiffs.

"Under Texas law, a manufacturer must instruct consumers as to the safe use of its product and warn consumers of the dangers of which it has actual or constructive knowledge at the time

the product is sold." *Pustejovsky v. Pliva, Inc.*, 623 F.3d 271, 276 (5th Cir. 2010) (citing *Pavlides v. Galveston Yacht Basin, Inc.*, 727 F.2d 330, 338 (5th Cir. 1984)). The learned-intermediary doctrine shields prescription-drug manufacturers from liability when a plaintiff sues for failure to warn of a drug's effects. *Id.* "The learned-intermediary doctrine states that, in some situations, a warning to an intermediary fulfills a supplier's duty to warn consumers." *Ackermann v. Wyeth Pharm.*, 526 F.3d 203, 207 (5th Cir. 2008). Because the prescribing physician evaluates the risks and benefits of available drugs for a particular patient, and because that physician is best able to pass on warnings from the manufacturer and to supervise the drug's use, *id.*, "the manufacturer's or supplier's duty to warn end users of the dangerous propensities of its product is limited to providing an adequate warning to an intermediary, who then assumes the duty to pass the necessary warnings on to the end users," *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 154 (Tex. 2012) (citations omitted). As long as the manufacturer sufficiently warns the prescribing or treating physician—the learned intermediary—the manufacturer is not liable for the intermediary's failure to warn the ultimate consumer. *Ackermann*, 526 F.3d at 207.

**a. Whether the Learned-Intermediary Doctrine Applies**

Juno previously moved to dismiss based on the learned-intermediary doctrine. (Docket Entry No. 43). The court denied the motion, concluding that it was premature to apply the doctrine at the pleadings stage and that a more complete record was needed. *Butler*, 2019 WL 2568477. In particular, the court highlighted uncertainty as to whether, under Texas law, a financial relationship between a prescribing physician and a drug manufacturer affects the doctrine's applicability and whether Texas courts would apply the doctrine in the clinical-trial context. *Id.* at *19. Juno now argues that, based on the undisputed facts in the fuller record, the learned-intermediary doctrine applies as a matter of law. (Docket Entry No. 100 at 12–21).

The record shows that Juno did not compensate Dr. Wierda or Dr. Rytting for their roles as investigators in the Rocket Study and did not affect their independent medical judgment. Juno paid MD Anderson certain of its costs for conducting the Rocket Study, but it did not pay Dr. Wierda or Dr. Rytting for any work on the Rocket Study. (Docket Entry No. 121-1 at 8, 21, 23 (sealed)). Dr. Wierda testified that Juno paid MD Anderson some costs for research-related testing and salary support for the Study staff. (Docket Entry No. 115-5 at 83 (sealed)). He also testified that Juno paid him $4,000 for consultations in October and November 2014,[6] but that both were unrelated to the Rocket Study. This was the only compensation that he had received from Juno. (*Id*. at 84). Dr. Rytting testified that Juno did not pay him for the Rocket Study. (Docket Entry No. 104-27 at 112 (Exh. 77) (sealed)). Dr. Wierda and Dr. Rytting testified that they exercised independent medical judgment in treating Holland. (*Id.* at 112–13, 222 (Exhs. 77, 83) (sealed)).

The plaintiffs have not identified record evidence showing that Juno compensated Dr. Wierda or Dr. Rytting or otherwise affected their independent medical judgments. As a result, the court need not decide whether Texas courts would apply the learned-intermediary doctrine to a drug manufacturer that did pay a physician to prescribe its drug. The court notes, however, that the Eastern District of Texas previously concluded that this set of facts would likely not affect the application of the doctrine:

> [A]s long as a physician-patient relationship exists, failure by the physician to advise the patient of the hazards of a prescription drug will not bar application of the doctrine. Moreover, if any physician allowed himself to become a mere conduit for [a manufacturer's] materials, then it is the physician who is responsible. By the same token, [a manufacturer] cannot remove a physician from the decision making process, only the physician can do that by avoiding his responsibility to make an individualized balancing

[6] The informed-consent form that Holland signed in May 2016 stated that Dr. Wierda received compensation from Juno as a consultant. (Docket Entry No. 104-2 at 22 (sealed)). Dr. Wierda testified that the basis for this statement was Juno's $4,000 payment for his 2014 consultations. (Docket Entry No. 115-5 at 84 (sealed)).

> of the risks and benefits associated with a drug and to advise the patient of possible adverse reactions.

*In re Norplant Contraceptive Prod. Liab. Litig.*, 955 F. Supp. 700, 706 (E.D. Tex. 1997), *aff'd*, 165 F.3d 374 (5th Cir. 1999) (citing *Hurley v. Lederle Labs.*, 863 F.2d 1173, 1178–79 (5th Cir. 1988)).

Juno argues that, under Texas law, courts apply the learned-intermediary doctrine so long as the intermediary physician exercised independent medical judgment. (Docket Entry No. 100 at 15). Texas law does not tie the doctrine's protection to the specific conduct of the physician. Rather, the protection is triggered by the presence of a physician-patient relationship. So long as a physician-patient relationship exists and the manufacturer sufficiently warned the physician, the manufacturer is not liable to the patient for failure to warn, even if the physician did not adequately warn the patient or exercise independent medical judgment. *See, e.g.*, *Pustejovsky v. Wyeth, Inc.*, No. 4:07-CV-103-Y, 2009 WL 3336032, at *2 (N.D. Tex. Sept. 4, 2009), *aff'd sub nom. Pustejovsky v. Pliva, Inc.*, 623 F.3d 271 (5th Cir. 2010); *Wyeth-Ayerst Lab'ys Co. v. Medrano*, 28 S.W.3d 87, 92 (Tex. App. 2000); *Bean v. Baxter Healthcare Corp.*, 965 S.W.2d 656, 662 (Tex. App. 1998) (citing *Hurley*, 863 F.2d at 1179, and *Swayze v. McNeil Lab. Inc.*, 807 F.2d 464, 471–72 (5th Cir. 1987)); *In re Norplant*, 955 F. Supp. at 706; *Baker v. Smith & Nephew Richards, Inc.*, No. 95-58737, 1999 WL 811334, at *24 (Tex. Dist. Ct. June 7, 1999), *aff'd sub nom. McMahon v. Smith & Nephew Richards, Inc.*, No. 14-99-00616-CV, 2000 WL 991697 (Tex. App.—Houston [14th Dist.] July 20, 2000, no pet.).

The issue this record and motion present is whether the Texas Supreme Court would apply the learned-intermediary doctrine in the clinical-trial context. The court previously stated that Texas did not "provide clear guidance on applying the learned-intermediary doctrine to clinical trials of non-FDA approved drugs in experimental phases." *Butler*, 2019 WL 2568477, at *15.

"In the absence of a controlling decision" by the state's highest court, the court must "make an '*Erie [R.R. Co. v. Tompkins*, 304 U.S. 64 (1938)] guess' as to how the state's highest court would resolve the issue." *In re Franchise Servs. Of N. Am., Inc.*, 891 F.3d 198, 209–10 (5th Cir. 2018), *as revised*, (June 14, 2018) (quoting *Temple v. McCall*, 720 F.3d 301, 307 (5th Cir. 2013)).

The plaintiffs argue that Texas courts have limited the learned-intermediary doctrine to the context of prescription drugs and that, because JCAR015 is not a prescription drug, the doctrine does not apply. (Docket Entry No. 126 at 24–30). But Texas courts have not so limited the doctrine. In *Seifried v. Hygienic Corp.*, 410 S.W.3d 427, 432 (Tex. App.—Houston [1st Dist.] 2013, *reh'g den.*), the Texas Court of Appeals concluded that the doctrine protected a manufacturer of elastic resistance bands used for physical therapy because the manufacturer adequately warned physical therapists who used the bands to treat patients. The court stated that, "like a doctor prescribing drugs, a physical therapist designing and supervising a physical therapy regimen can pass on applicable warnings to the patient, based on the patient's physical condition and particular needs." *Id.* In *Bean v. Baxter Healthcare Corp.*, 965 S.W.2d 656, 663 (Tex. App.—Houston [14th Dist.] 1998, no writ), the Texas Court of Appeals applied the learned-intermediary doctrine to shield the manufacturer of silicone breast implants, finding "no basis for distinguishing silicone implants from prescription drugs for purposes of applying the doctrine; in both instances, the product is manufactured for administration only by a physician or other authorized person." Similarly, in *Porterfield v. Ethicon, Inc.*, 183 F.3d 464 (5th Cir. 1999) (per curiam), the Fifth Circuit, applying Texas law, affirmed the trial court's grant of summary judgment for the manufacturer of a surgical mesh product, based on the learned-intermediary doctrine.

In *Centocor*, the Texas Supreme Court stated that "the learned intermediary doctrine applies particularly to the medical field and to unavoidably unsafe products like prescription drugs,

which, by law, cannot go from the manufacturer to the end user except through a prescribing physician." 372 S.W.3d at 165 (citing *Restatement (Second) of Torts* § 402A cmt. K.). The elastic resistance bands used by physical therapists in *Seifried*, the silicone breast implants prescribed in *Bean*, and the surgical mesh prescribed in *Porterfield*, like prescription drugs, were medical products that could not reach their end users except through treating medical professionals. These cases support the conclusion that Texas law does not limit the learned-intermediary doctrine to FDA-approved prescription drugs.

The question remains how the doctrine applies to the context of experimental drugs prescribed by physicians and administered in a clinical trial. The court considers the existence of physician-patient relationship, (2) the physician's involvement selecting the product, and (3) the physician's "superior understanding of the interplay between the product's dangers and the patient's condition." *Carpenter v. Bos. Sci. Corp.*, No. 3:18-CV-02338-L, 2019 WL 3322091, at *8 (N.D. Tex. July 24, 2019) (quoting *Dyer v. Danek Med., Inc.*, 115 F. Supp. 2d 732, 740 (N.D. Tex. 2000)); *Guzman v. Synthes (USA)*, 20 S.W.3d 717, 720 n.2 (Tex. App. 1999).

The record evidence shows a physician-patient relationship between Holland and Dr. Wierda and Dr. Rytting. Bayer testified that Dr. Rytting was Holland's primary treating physician at MD Anderson. (Docket Entry No. 104-27 at 20 (Exh. 67) (sealed)). Dr. Rytting performed a bone-marrow aspiration on Holland, physically examined her, ordered other tests, and discussed treatment options with her and her mother. (Docket Entry No. 112-3 at 35; Docket Entry No. 104-14 (Exh. 20) (sealed)). After M.K. died, Holland and Butler met with Dr. Wierda, who discussed the cause of M.K.'s death and the related risks of JCAR015. Dr. Wierda gave his opinion on whether Holland could still receive JCAR015, and he asked her if she still wanted to do so. (Docket Entry No. 112-3 at 48–49; Docket Entry No. 104-27 at 212–15 (Exh. 83) (sealed)).

The record evidence shows that Dr. Wierda and Dr. Rytting were integrally involved in selecting JCAR015 to treat Holland's aggressive, terminal cancer. At the initial meeting with Holland and Butler, Dr. Rytting discussed treatment options, including three CAR-T therapy trials. (Docket Entry No. 112-3 at 35). In response to Butler's question about what Dr. Rytting would do if Holland were his child, he answered that he would send her to the Children's Hospital of Philadelphia for a clinical trial of a CAR T-cell drug taking place there. (*Id.*). After discussing these options, Dr. Rytting presented Holland's case to MD Anderson's adult leukemia team to determine her eligibility for the Rocket Study. (*Id.*; Docket Entry No. 104-14 at 10 (Exh. 20) (sealed)). As the principal investigator, Dr. Wierda was responsible for all patients enrolled in the Rocket Study. After M.K. died, Dr. Wierda met with Holland and Butler to discuss both his comfort with proceeding to treat Holland with JCAR015 and her willingness to receive the treatment. Without Dr. Rytting and Dr. Wierda, Holland could not have received the JCAR015 treatment.

Finally, the record shows that Dr. Wierda and Dr. Rytting had a medical understanding of Holland's condition and the risks associated with JCAR015. Dr. Rytting reviewed Holland's medical records and conducted repeated testing to determine the nature and stage of her disease and her overall condition and identify potential treatment options. To determine if she was eligible for the Rocket Study, Holland underwent numerous tests, including a pulse-oximetry test, a neurological exam, x-rays, an electrocardiogram, blood tests, and urine tests. (Docket Entry No. 104-2 at 2 (Exh. 1) (sealed)). Dr. Wierda and Dr. Rytting knew much about Holland's condition before finding her eligible to receive JCAR015.

Dr. Wierda and Dr. Rytting also knew much about the risks of JCAR015. In September 2015, Dr. Wierda attended a principal-investigators meeting that Juno held. (Docket Entry

No. 104-11 (Exh. 13) (sealed)). At that meeting, Juno gave a presentation on the Rocket Study that included a discussion on the "[p]otential for increased incidence of toxicities associated with CAR T cell expansion," which included cytokine release syndrome. (*Id.* (Exh. 14) (sealed)).

In December 2015, Juno sent Dr. Wierda an amended Rocket Study protocol. Docket Entry No. 104-16 (Exh. 38) (sealed). The amended protocol discussed "potential risks and management of treatment toxicities" and dedicated four pages to cytokine release syndrome. (Docket Entry No. 104-9 at 55–59 (sealed)). After M.K. died due to cytokine release syndrome, Juno updated its protocol and discussed it with the principal investigators, including Dr. Wierda, who then discussed the cause of M.K.'s death and the risks of JCAR015 with Holland and Butler. Dr. Wierda and Dr. Rytting understood both Holland's condition and the risks JCAR015 posed for her.

Based on Texas and Fifth Circuit case law, the court concludes that the Texas Supreme Court would likely apply the learned-intermediary doctrine on the factors established in the record.

**b. Applying the Learned-Intermediary Doctrine**

To overcome the learned-intermediary doctrine, the plaintiffs must show that the warning Juno provided to Dr. Wierda and Dr. Rytting was defective and that the defect was "a producing cause of [Holland's] injury." *Ackermann*, 526 F.3d at 208. The plaintiffs "must show that, but for the inadequate warning, [Holland's] doctors would have recommended different treatment, or provided additional warnings that would have led [Holland] to withhold consent." *In re DePuy Orthopaedics, Inc., Pinnacle Hip Implant Prod. Liab. Litig.*, 888 F.3d 753, 774 (5th Cir. 2018) (citing *Ackermann*, 526 F.3d at 208, 214, and *McNeil v. Wyeth*, 462 F.3d 364, 373 (5th Cir. 2006)). "The issue is generally a fact question, but 'when the prescribing physician is aware of the product's risks and decides to use it anyway, any inadequacy in the product's warnings, as a matter

of law, is not the producing cause of the patient's injuries." *Id.* (brackets omitted) (quoting *Centocor*, 372 S.W.3d at 170). "When a warning specifically mentions the circumstances complained of, the warning is adequate as a matter of law." *McNeil*, 462 F.3d at 368 (quotation marks omitted).

The plaintiffs argue that Juno failed to adequately warn Dr. Wierda because Juno did not tell him about the manufacturing changes that it made to 1928z to make JCAR015. (Docket Entry No. 126 at 30–32). But the plaintiffs identify no record evidence that supports finding that, if Dr. Wierda or Dr. Rytting knew of the manufacturing changes, they would have recommended a different treatment for Holland or provided additional warnings that would have led Holland to pursue a different treatment. As noted above, Juno repeatedly warned Dr. Wierda that JCAR015 carried a risk of cytokine release syndrome. Before Holland was treated with JCAR015, Juno warned Dr. Wierda of the risk of cerebral edema caused by cytokine release syndrome. Holland died from those conditions following her JCAR015 treatment. As a matter of law, Juno did not fail to warn Dr. Wierda. *See McNeil*, 462 F.3d at 368. Under Texas law, the learned-intermediary doctrine applies to "any claim predicated on the alleged inadequacy of a product's warning." *Perez v. Am. Med. Sys. Inc.*, 461 F. Supp. 3d 488, 507 (W.D. Tex.) (citing *Centocor*, 372 S.W.3d at 169). Juno is entitled, as a matter of law, to summary judgment on the plaintiffs' failure-to-warn claims.

**2. Texas Civil Practice and Remedies Code § 82.007**

Juno argues that it is entitled to summary judgment under § 82.007 of the Texas Civil Practice and Remedies Code, which states, in relevant part:

> (a) In a products liability action alleging that an injury was caused by a failure to provide adequate warnings or information with regard to a pharmaceutical product, there is a rebuttable presumption that the defendant or defendants, including a health care provider, manufacturer, distributor, and prescriber, are not liable with respect to the allegations involving failure to provide adequate warnings or information if:

> (1) the warnings or information that accompanied the product in its distribution were those approved by the United States Food and Drug Administration for a product approved under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Section 301 et seq.), as amended, or Section 351, Public Health Service Act (42 U.S.C. Section 262), as amended;

TEX. CIV. PRAC. & REM. CODE § 82.007.[7]

In its motion to dismiss, Juno argued that § 82.007 applied because the FDA had approved the warnings that accompanied JCAR015. Following *Rodriguez v. Gilead Scis., Inc.*, No. 2:14-CV-324, 2015 WL 236621, at *7 (S.D. Tex. Jan. 16, 2015), the court deferred the issue until summary judgment. *Butler*, 2019 WL 2568477, at *22. *Rodriguez* concluded that determining whether § 82.007 applied to an FDA-approved clinical trial and the FDA-approved warnings that accompanied that trial required "evidence of precisely what materials were provided to the FDA and whether the warnings on which [the drug manufacturer] relie[d] were 'approved.'" 2015 WL 236621, at *7. The court noted that under § 82.007, "any approval by the FDA, acting pursuant to the [Federal Food, Drug, and Cosmetic] Act would create the non-liability presumption in favor of [the drug manufacturer]." *Id.*

The plaintiffs argue that § 82.007 does not apply to nonapproved experimental drugs undergoing FDA-approved clinical trials. (Docket Entry No. 126 at 32 (citing Docket Entry No. 25 at 16–19)). *Rodriguez* disagreed with that interpretation, concluding that "any approval by the FDA," including approval for a clinical trial, would trigger § 82.007. *Rodriguez* is persuasive and the plaintiffs identify no contrary authority.

Juno argues that § 82.007 applies because it filed an Investigator's Brochure and a Study

[7] A "products liability action" is defined as "any action against a manufacturer or seller for recovery of damages arising out of personal injury, death, or property damage allegedly caused by a defective product whether the action is based in strict tort liability, strict products liability, negligence, misrepresentation, breach of express or implied warranty, or any other theory or combination of theories." TEX. CIV. PRAC. & REM. CODE § 82.001(2)

protocol with the FDA as part of its Investigational New Drug Application. Because those materials contained warnings about JCAR015's risks of toxicity, including from cytokine release syndrome, and the FDA approved those materials when it approved the Application, Juno argues that the FDA approved those warnings, triggering § 82.007.

The record evidence does not support Juno's argument. The record shows that Juno submitted an Investigator's Brochure and a Study protocol as part of its Investigational New Drug Application. (Docket Entry No. 104-15 (Exh. 26) (sealed); Docket Entry No. 104-21 (sealed)). The FDA approved the Application in July 2015. (Docket Entry No. 104-14 (Exh. 21) (sealed)). But the record does not provide the contents of the brochure or the Study protocol submitted to the FDA. The brochure and Study protocol that Juno relies on, and that the record contains, were issued in October and December 2015, after the FDA approved Juno's Application. (Docket Entry No. 104-9 at 2 (sealed); Docket Entry No. 104-10 at 2 (sealed)). Although these materials include warnings about cytokine release syndrome, (Docket Entry No. 104-9 at 55 (sealed); Docket Entry No. 104-10 at 40 (sealed)), the record does not specifically show that those warnings were included in the version of those materials that the FDA approved. Because the record does not show that Juno's warnings about cytokine release syndrome were approved by the FDA, Juno is not entitled to summary judgment on the basis of § 82.007 of the Texas Civil Practice and Remedies Code.

**3. Causation**

Juno argues that, even if the learned-intermediary doctrine does not apply and Juno owed Holland a duty to warn of the risks of JCAR015, summary judgment would still be warranted because the plaintiffs have not identified record evidence supporting an inference that inadequate warnings led to Holland's death. (Docket Entry No. 100 at 33); *see Centocor*, 372 S.W.3d at 172 n.31 (even if the learned-intermediary doctrine did not bar the plaintiffs' claims, "causation is a

necessary element of all [their] claims" based on a drug manufacturer's alleged failure to warn); *McKinley v. Stripling*, 763 S.W.2d 407, 410 (Tex. 1989) (to "establish that the failure to obtain informed consent was a proximate cause of [a plaintiff's] injuries," the plaintiff must show that "a reasonable person" would have "refused the treatment . . . had he been fully informed of all inherent risks which would influence his decision.").

Juno points to the informed-consent form that Holland signed, acknowledging that JCAR015 could "result in hospitalization and/or death." (Docket Entry No. 104-2 at 11, 26 (Exh. 1) (sealed)). Juno also points to the evidence of Dr. Wierda's discussion with Holland and Butler about her risks of cytokine release syndrome after M.K.'s death. Juno finally relies on the testimony of the plaintiffs' experts, Dr. David Karpf and Dr. Gail Van Norman, that, despite alleged problems with the informed-consent form that Holland signed, a reasonable person in Holland's position would not have decided against enrolling in the Rocket Study if the form was changed. (Docket Entry No. 104-27 at 86 (Exh. 73) (sealed) (Dr. Karpf: "any given change" in the form's presentation of JCAR015's side effects would not "have made a compelling difference" on the enrollment decision); Docket Entry No. 104-27 at 177 (Exh. 82) (sealed) (Dr. Van Norman: changing the description of the Study from "Phase 2" to "first in-human study" would not cause a reasonable person to not enroll)).

In response, the plaintiffs rely on Butler's testimony that Holland would not have participated in the Rocket Study had she received more warnings about cytokine release syndrome and cerebral edema. (Docket Entry No. 112-3 at 14). Butler's testimony does not create a genuine factual dispute material to determining whether a reasonable person in Holland's position would have decided against participating in the Study had Juno provided different or additional warnings. The record fails to support a reasonable inference that, with added language on the cytokine release

syndrome and cerebral edema risks, a reasonable person in Holland's shoes would have decided against enrolling in the Rocket Study.

Juno is entitled to judgment as a matter of law, based on the undisputed facts, on the plaintiffs' failure-to-warn claims.

**4. The Negligence Claims**

Juno argues that summary judgment is warranted on the negligence claims because the plaintiffs have not identified record evidence that supports an inference that Juno breached a duty to Holland by not conducting and concluding a Phase 1 clinical trial of JCAR015 before the Rocket Study. To show that Juno breached a duty owed to Holland, the plaintiffs must show that Juno either "did something an ordinarily prudent person exercising ordinary care would not have done under the circumstances, or . . . failed to do that which an ordinarily prudent person would have done in the exercise of ordinary care." *Boudreaux v. Swift Transp. Co.*, 402 F.3d 536, 541 (5th Cir. 2005) (citation omitted).

Juno sought approval for its Phase 2 clinical trial from the FDA, collaborated with the FDA on the trial's protocols, adjusted the protocol based on FDA feedback, and got approval from the FDA to conduct the Rocket Study as a Phase 2 clinical trial. The plaintiffs have not identified evidence supporting an inference that an "ordinarily prudent" drug manufacturer, exercising ordinary care, would have done differently.

Juno also argues that summary judgment is warranted on the negligence claims because the plaintiffs have not identified evidence showing that Holland's death was caused by Juno's decision not to conduct a Phase 1 clinical trial before conducting the Rocket Study. *See Id.* at 540–41 (to establish a negligence claim, the plaintiff must show that the defendant's negligence "was the actual cause of the [plaintiff's] injuries."). The plaintiffs argue that Juno would have had

more accurate information about JCAR015's risks and side effects after conducting a Phase 1 trial and that Holland's decision to enroll in the Rocket Study would have been affected by that information. But, as discussed above, the record evidence shows that more warnings on the risks that were already identified would not have affected the enrollment decision by a reasonable person in Holland's circumstances.

Because the plaintiffs have not identified record evidence that supports essential elements of their negligence claims, Juno is entitled to summary judgment, as a matter of law, on those claims.[8]

**B. The Fraud Claims**

The plaintiffs assert two grounds for fraud: (1) Dr. Wierda's alleged misrepresentations of JCAR015's risks; and (2) the informed-consent form that Holland signed.[9] (Docket Entry No 76 at ¶¶ 72, 121; Docket Entry No. 57). Juno asserts that it is entitled to summary judgment on the fraud claims because it made no false material representations to Holland. (Docket Entry No. 100 at 35).

Dr. Wierda was not Juno's agent or employee. The record evidence shows that Juno did not pay Dr. Wierda for the Rocket Study; Dr. Wierda worked for MD Anderson. Although Dr. Wierda had briefly been a consultant for Juno in the past, that work was unrelated to the Rocket Study and had ended over a year before Holland was referred to MD Anderson for cancer treatment.

The plaintiffs argue that the informed-consent form's statement that the Rocket Study was

[8] Juno also argues that the negligence claims are preempted by the federal regulatory scheme that governs FDA-approved clinical trials. Because the claims fail as a matter of state law, the court declines to reach the preemption issue.

[9] Juno disputes that it wrote or approved of the informed-consent form that Holland signed. Because the record evidence does not support the plaintiffs' claims, the court need not consider whether Juno created or approved the form.

"an early study of JCAR015, so the side effects are not well known," was fraudulent because: (1) multiple patients had died in the JCAR015 clinical trials; and (2) Juno's annual reports, issued before Holland signed the informed-consent form, showed numerous severe side effects. (Docket Entry No. 76 at ¶ 72).

The first theory amounts to a fraud-by-omission claim, which is foreclosed by the learned-intermediary doctrine. *See Centocor*, 372 S.W.3d at 169. The second theory is that Juno affirmatively misrepresented the state of knowledge of JCAR015's risks. The Texas Supreme Court in *Centocor* decided not to reach the issue of whether the learned-intermediary doctrine applies to affirmative misrepresentations. *Id*. at 169 n.30. Federal district courts appear to disagree on whether the doctrine applies to such claims, but the courts have not analyzed the issue. *See McKay v. Novartis Pharms. Corp.*, 934 F. Supp. 2d 898, 912 (W.D. Tex. 2013), *aff'd*, 751 F.3d 694 (5th Cir. 2014) (reading *Centocor* as "suggest[ing] that a claim based on an affirmative misrepresentation . . . would not be regarded as a claim premised on failure to warn"); *Romero v. Wyeth Pharms., Inc.*, No. 1:03-CV-1367, 2012 WL 12547449, at *2 (E.D. Tex. Aug. 31, 2012) ("[The plaintiff] asserts that *Centocor* . . . is distinguishable because, in that case, the plaintiff's fraud claim was based on side effects wholly omitted from a drug's label, while this action deals with affirmative misrepresentations. The court finds this distinction immaterial.").

The court need not determine whether the learned-intermediary doctrine applies to the plaintiffs' fraud claims based on affirmative misrepresentations, because the record evidence does not support an inference that Holland was injured due to Juno's alleged misrepresentations. To succeed on their fraud claims, the plaintiffs must show, among other things, that Juno made a material representation that was false, Holland relied on that representation, and she was injured as a result. *N. Cypress Med. Ctr. Operating Co., Ltd. v. Aetna Life Ins. Co.*, 898 F.3d 461, 473–74

(5th Cir. 2018). "A false representation is material if a reasonable person would attach importance to and be induced to act on the information." *Shandong Yinguang Chem. Indus. Joint Stock Co. v. Potter*, 607 F.3d 1029, 1033 (5th Cir. 2010) (per curiam) (citing *Citizens Nat'l Bank v. Allen Rae Invs.*, 142 S.W.3d 459, 478–79 (Tex. App.—Fort Worth 2004, no pet.)).

The plaintiffs allege that Juno misrepresented JCAR015's risks in the informed-consent form that Holland signed. The record evidence shows that Holland and Butler had significant information about the risks before and after M.K.'s death and agreed to continue participating in the Rocket Study after receiving that information. The plaintiffs' expert, Dr. Karpf, testified that "any given change" in the informed-consent form's presentation of JCAR015's side effects would not "have made a compelling difference" on a reasonable person's enrollment decision. (Docket Entry No. 104-27 at 86 (Exh. 73) (sealed)). The plaintiffs identify no evidence, other than Butler's speculation, that Holland would not have enrolled in the Rocket Study if the informed-consent form had more information about JCAR015's side effects.

Juno is entitled to summary judgment, as a matter of law, on the plaintiffs' fraud claims.

## IV. Conclusion

Juno's motion for summary judgment, (Docket Entry No. 100), is granted. Final judgment is entered by separate order.

SIGNED on May 27, 2021, at Houston, Texas.

Lee H. Rosenthal
Chief United States District Judge